



Policies and Procedures
TOPIC: Patient Opt-Out Choice and Meaningful Disclosure
Policy #: TBD
Effective Date: TBD

## **I. BACKGROUND AND PURPOSE**

The purpose of this policy is to describe how at the point of care the consent decisions of patients to participate or not participate in the Illinois Health Information Exchange (ILHIE) may be meaningfully exercised. The policy will also describe how these consent decisions by patients may be subsequently changed.

## **II. POLICY**

The ILHIE will offer all patients a meaningful and informed way to decide whether to participate or not participate in its State-wide health information exchange. This patient consent process will be governed by an “Opt-Out” policy and administered by providers and provider organizations at the point of care. This means that all patients of a provider or provider organization that participates in the ILHIE will be automatically enrolled in the ILHIE, and no affirmative action will need to be taken by patients to establish their consent, unless a patient’s personal health information contains categories of “specially protected” health information requiring specific written authorization under Federal and State laws. A patient shall be deemed to have given his or her consent to participate unless and until the patient affirmatively opts-out of the ILHIE.

To ensure that patients are able to make meaningful and informed choices about their participation in the ILHIE, each patient will receive a written Notice from his or her participating provider or organization during the first patient encounter after the participating provider or organization enrolls in the ILHIE. This Notice will be developed and approved by the ILHIE and will explain the function of the health information exchange, the purposes for disclosure of the patient’s protected health information to other participating providers or organizations, and the potential benefits and risks of participation in the exchange.

If a patient does not opt-out of the ILHIE, his or her protected health information will generally be disclosed in response to a specific request, or query, made by a participating provider or organization for a permissible purpose. However, a patient’s protected health information will not be disclosed in response to such a query when it contains “specially protected” health information unless specific written authorization is given by the patient to the participating provider or organization for the disclosure of such information in the ILHIE or the participating provider or organization can ensure that no such information will be available through the ILHIE.

A patient who does not want his or her protected health information to be disclosed to other participating providers or organizations may opt-out by following the procedures below. If a

patient does opt-out, his or her protected health information will not be disclosed through the ILHIE for any purpose except as permitted by law such as public health reporting.

A patient may decide at any time to change his or her consent preference to participate or not to participate in the ILHIE, including the revocation of a prior decision to opt-out of participation in the ILHIE.

### **III. PROCEDURES**

#### **A. Patient Procedures.**

1. No action is needed by a patient of a participating provider or provider organization if he or she wishes to participate in the ILHIE. A patient shall be deemed to have given his or her consent to participate unless and unless the patient affirmatively opts-out of the ILHIE. These alternatives shall be collectively referred to herein as the patient's consent decision.

2. Every patient must receive a Notice about the ILHIE from his or her participating provider or organization during his or her first encounter with that provider or organization after it enrolls in the ILHIE. This Notice must be provided in writing, and in the form developed and approved by the ILHIE which explains:

- (i) the function of the ILHIE;
- (ii) the purposes for which a patient's protected health information may be disclosed to other participating providers or organizations through the ILHIE;
- (iii) the types of protected health information which may be disclosed to other participating providers and organizations;
- (iv) the need for the patient's specific written authorization to disclose certain categories of "specially protected" health information;
- (v) the fact that a patient's personal demographic information will be included in a Master Patient Index maintained by the ILHIE to permanently record his or her consent decision;
- (vi) the potential benefits and risks of participation in the ILHIE; and
- (vii) the fact that a patient's participation in the ILHIE is voluntary and subject to a patient's right to opt-out.

3. An identical Notice about the ILHIE will be available to patients on-line at the ILHIE's website.

4. The identity of each patient receiving the Notice must be verified by the participating provider or organization, including the accuracy of all personal demographic information of that patient.

5. A patient may opt-out of participation in the ILHIE through his or her participating provider or organization. If available at a future date on the ILHIE's website, the patient may opt-out by registering his or her opt-out decision on-line.
6. A patient may opt-out of the health information exchange during a visit or encounter with his or her participating provider or organization.
7. Prior to opting-out, a patient must first be presented with a copy of the ILHIE's written Notice.
8. After a patient's identity has been verified by the participating provider or organization, and after the patient has been presented with a copy of the written Notice, then a patient may opt-out of participation in the ILHIE by executing a standard opt-out form developed and approved by the ILHIE for use by participating providers and organizations to document the patient's opt-out decision.
9. A patient may choose to opt-out at any time, even after having already been enrolled in the ILHIE. However, any exchange of protected health information that may have occurred prior to a patient's decision to opt-out will not be reversed.
10. A patient may revoke his or her decision to opt-out of the ILHIE by completing a written revocation form available from his or her participating provider or organization. If available at a future date on the ILHIE's website, the patient may revoke his or her decision to opt-out by registering his or her revocation decision on-line.
11. Once the revocation form has been executed by the patient and communicated to the ILHIE by the patient's participating provider or organization, he or she will be enrolled in the ILHIE from that date forward.
12. A parent or legal guardian may express the consent decision of a minor child under the age of 18 to opt-out of the ILHIE only through the minor child's participating provider or organization. If deemed necessary by the participating provider or organization, a parent or legal guardian may be required to present the provider or organization with a proof of legal guardianship or other legal authority to act on behalf of a child.
13. A minor may be presumed legally capable of making his or her own consent decision when seeking treatment for substance abuse, birth control, prenatal care, or a sexually transmitted disease.
14. Upon reaching the age of majority, a patient whose consent decision was previously expressed by his or her parent or legal guardian will be given the opportunity to exercise his or her own consent decision in accordance with the procedures outlined in paragraphs 1 through 11 above.

B. Participating Provider and Organization Procedures.

1. Each participating provider or organization must provide every patient with a Notice about his or her participation in the ILHIE during the patient's first visit or encounter with that participating provider or organization after it enrolls in the ILHIE. This Notice must be provided in writing, and in the form developed and approved by the ILHIE which explains:

- (i) the function of the ILHIE;
- (ii) the purposes for which a patient's protected health information may be disclosed to other participating providers or organizations through the ILHIE;
- (iii) the types of protected health information which may be disclosed to other participating providers or organizations;
- (iv) the need for the patient's specific written authorization to disclose certain categories of "specially protected" health information;
- (v) the fact that the patient's personal demographic information will be included in a Master Patient Index maintained by the ILHIE to permanently record his or her consent decision;
- (vi) the potential benefits and risks of participation in the ILHIE; and
- (vii) the fact that a patient's participation in the ILHIE is voluntary and subject to a patient's right to opt-out.

2. This written Notice may be provided to the patient as an addendum to the participating provider's or organization's Notice of Privacy Practices. The participating provider or organization is encouraged to record the delivery of the Notice in the patient's medical record.

3. The participating provider or organization may also include a copy of the Notice on its own website, if any, and display any other written notice made available by the ILHIE in a public area of the participating provider's or organization's facility.

4. The identity of each patient receiving the Notice must be verified by the participating provider or organization, including the accuracy of all personal demographic information of that patient.

5. If the patients ask questions about the ILHIE, the participating provider or organization must verbally counsel the patient about the contents of the Notice. The goal of such counseling will be to educate the patient about the potential benefits and risks of participation in the ILHIE, while at the same time, to fully respect the individual consent decision expressed by the patient.

6. Once a patient has been provided with a copy of the written Notice by a participating provider or organization, it is not necessary for that provider or organization to repeat the process.

7. If a patient elects to opt-out of the ILHIE, and the patient's identity has been verified by the participating provider or organization, the provider or organization will require the patient to document his or her decision to opt-out by utilizing the standard opt-out form developed and approved by the ILHIE. A copy of this opt-out form will be kept and maintained by the participating provider or organization in the patient's medical record in accordance with the provider or organizations own policies.
8. A participating provider or organization must allow a patient to opt-out at any time, even after having already been enrolled in the ILHIE. However, any exchange of protected health information that may have occurred prior to a patient's decision to opt-out will not be reversed.
9. If requested, a participating provider or organization will assist the patient in revoking his or her decision to opt-out of the ILHIE. The provider or organization will supply the patient with the standard revocation form developed and approved by the ILHIE. The participating provider or organization will keep and maintain a copy of this signed revocation form in the patient's medical record in accordance with its own policies.
10. Once the revocation form has been executed by the patient and communicated by the participating provider or organization to the ILHIE, he or she will be enrolled in the ILHIE from that date forward.
11. Participating providers and organizations who have agreed to requests made by their patients for restrictions on the disclosure of "specially protected" health information under Federal and State law, such as information regarding alcohol and substance abuse treatment, HIV/AIDS testing and genetic testing, will honor those requests and ensure that their EHRs, if capable, will not make such information available through the ILHIE. If a participating provider's or organization's EHR is incapable of ensuring that such information will not be made available through the ILHIE, then the provider or organization instead will require the patient to opt-out of participation in the ILHIE.
12. The participating provider or organization will comply with the consent decision made by a parent or legal guardian for his or her minor child to opt-out of the ILHIE. If deemed necessary by the participating provider or organization, a parent or legal guardian may be required to present the provider or organization with a proof of legal guardianship or other legal authority to act on behalf of a child.
13. A minor may be presumed legally capable of making his or her own consent decision when seeking treatment for substance abuse, birth control, prenatal care, or a sexually transmitted disease.
14. Upon reaching the age of majority, a patient whose consent decision was previously expressed by his or her parent or legal guardian will be given the opportunity to exercise his or her own consent decision in accordance with the procedures outlined in paragraphs 1 through 10 above.

15. Upon enrollment in the ILHIE, a participating provider or organization will electronically supply the ILHIE with personal demographic information about all of its patients so that other participating providers and organizations may access their protected health information, if available, for a permissible purpose in accordance with the ILHIE's policies and procedures.

16. All decisions made by patients to opt-out of the ILHIE or revoke a prior decision to opt-out of the ILHIE will be immediately and electronically communicated by the participating provider or organization to the ILHIE to ensure compliance with each patient's decision to opt-out. For purposes of this Policy and Procedure, the term "immediately" shall mean within the same business day or as soon thereafter as practicable.

17. A participating provider or organization will not deny care to any patient solely because he or she elects to opt-out of the ILHIE.

C. ILHIE Procedures.

1. The ILHIE will provide outreach, educational information, and where requested, technical assistance to patients and participating providers and organizations to promote a consistent implementation of the consent procedures outlined above. At a minimum, the ILHIE's educational information must include a written Notice developed and approved by the ILHIE which explains:

- (i) the function of the ILHIE;
- (ii) the purposes for which a patient's protected health information may be disclosed to other participating providers and organizations through the ILHIE;
- (iii) the types of protected health information which may be disclosed to other Participating providers and organizations;
- (iv) the need for the patient's specific written authorization to disclose certain categories of "specially protected" health information;
- (v) the fact that the patient's personal demographic information will be included in a Master Patient Index maintained by the ILHE to permanently record his or her consent decision;
- (vi) the potential benefits and risks of participation in the ILHIE; and
- (vii) the fact that a patient's participation in the ILHIE is voluntary and subject to a patient's right to opt-out of participation in the ILHIE.

2. The ILHIE may prepare and distribute additional notices or materials for display by its participating providers and organizations in public areas that are designed to inform patients about the ILHIE and their right to opt-out of the ILHIE.

3. The ILHIE will include the written Notice, as well as other information designed to inform patients about the ILHIE and their right to opt-out of participation in the ILHIE, on its website.
4. The ILHIE will develop and provide its participating providers and organizations with templates of all standard opt-out forms, revocation forms, Notices, and other educational materials for purposes their distribution and use in providing their patients with meaningful disclosure about the ILHIE and a patient's right to opt-out of participation in the ILHIE. In addition, the ILHIE will include all of these forms, notices and other materials on its website.
5. The ILHIE may, in the future, make available to patients on its website an electronic process available to enable patients to opt-out of participation in the ILHIE. Any such on-line process would be designed by the ILHIE to elicit sufficient personal demographic information from the patient to verify his or her identity and have to employ methodologies and technologies to ensure proper patient verification.
6. If available, any such electronic on-line process would include access to the same information and materials as made available to patients by their participating providers and organizations, including the written Notice developed and approved by ILHIE. Prior to opting-out on-line, a patient would be required to acknowledge electronically that he or she has been presented with and understands the Notice.
7. A patient's election to opt-out either through a participating organization, or if available in the future, on-line at the ILHIE's website, will be immediately communicated to the ILHIE. The ILHIE will record the patient's decision to opt-out in its Master Patient Index.
8. A patient may revoke his or her decision to opt-out of the ILHIE at any time by completing a revocation form supplied by his or her participating provider or organization, or if available in the future, by completing an electronic revocation form on-line at the ILHIE's website. This must be a standard revocation form developed and approved by the ILHIE.
9. Once the revocation form has been executed by the patient and communicated to the ILHIE, he or she will be enrolled in the ILHIE from that date forward.
10. Upon enrollment in the ILHIE, a participating provider or organization will electronically supply the ILHIE with personal demographic information about all of its patients. The ILHIE will electronically maintain personal demographic information about all patients of participating providers and organizations in a Master Patient Index in order to record and maintain each patient's consent decision. In addition, the ILHIE will utilize this personal demographic information to enable other participating providers and organizations to access the protected health information of patients for a permissible purpose in accordance with the ILHIE's policies and procedures.
11. All decisions made by patients to opt-out of the ILHIE will be immediately and electronically recorded by the ILHIE to ensure compliance with each patient's decision to opt-out.

12. For a patient who has not opted-out of the ILHIE, the ILHIE will generally share all of a patient's health information that is available through the ILHIE in response to a query from a participating provider or organization.

13. A patient's protected health information will not be disclosed in response to a query when it contains "specially protected" health information for which a specific written authorization is required. Participating provider and organizations whose EHRs are incapable of ensuring that such information will not be made available through the ILHIE will require their patients with "specially protected" health information to opt-out of participation in the ILHIE.

14. For a patient who has opted-out of the ILHIE, the ILHIE will ensure that no protected health information will be disclosed except for any purpose except as permitted by law such as public health reporting. Instead, consistent with the patient's reasonable expectations, a message will be sent to the participating provider or organization that submitted the query that to the effect there is "no information available".